C. Furlow
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 7 1991

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM OF CONFERENCE

SUBJECT: PP#9F3743 - Clethodim (Select®) in/on Soybeans, Cottonseed, and Animal Commodities.
Review of Petitioner's Meeting Minutes of the EPA-Valent Meeting of April 16, 1991, and Conditional Registration Request.
(No MRID#) [DEB#7888] {HED Project #1-1069}

FROM: Francis D. Griffith Jr., Chemist
Chemistry Branch I-Tolerance Support
Health Effects Division (H-7509C)

THRU: Richard D. Schmitt, Ph.D., Chief
Chemistry Branch I-Tolerance Support
Health Effects Division (H-7509C)

TO: Joanne I. Miller, PM-23
Fungicide-Herbicide Branch
Registration Division (H-7505C)

and

Donald A. Marlow, Chief
Analytical Chemistry Branch
Biological and Economic Analysis Division (H7503C)

EXECUTIVE SUMMARY OF RESIDUE ANALYTICAL METHOD DEFICIENCIES

In order to reinitiate the Petition Method Validation (PMV) on the compound specific method the petitioner needs to provide recovery data as follows:

Milk S-methyl clethodim sulfoxide at 0.02 ppm and 0.05 ppm.

CONCLUSIONS:

1. The method validation data for S-methyl clethodim in milk using Method RM-26D-1 at the levels indicated above are required to reinitiate the PMV and to establish the proposed tolerance.

2. At a later time before the compound specific Method RM-26D-1 is published in PAM-II the petitioner needs to present additional recovery data as follows:

a. soybeans
sethoxydim sulfoxide and 5-hydroxysethoxydim sulfoxide at 1.0 ppm and 0.05 ppm.

b. milk
sethoxydim sulfoxide at 0.02 ppm.

3. The request for a meeting on granting a conditional registration is an issue for RD to decide.

4. The established sethoxydim tolerances in soybeans and fuzzy cottonseed are based on actual crop field trial residue data. The proposed clethodim tolerances in soybean and fuzzy cottonseed are based on actual crop field trial residue. The secondary tolerances in both poultry and eggs are based on results of the respective feeding studies.

5. Adding label language to prohibit use of Select® and Poast® on the same crop in the same growing season is helpful. CB points out this will not stop misuse, but will make it easier for enforcement agencies to successfully prosecute pesticide misuse cases.

DETAILED CONSIDERATIONS

Valent submitted a letter requesting a meeting to discuss a conditional registration of Select® Herbicide, and Attachment I which is their understanding of what transpired at April 16, 1991, meeting. Attachments II and III are copies of earlier Valent correspondence relating to residue analytical methods. CB will comment on Valent's meeting minutes, then their request for conferences on methods, and finally the conditional registration request.

CB agrees with the petitioner's discussion on clethodim product chemistry. CB did have concerns on which form of clethodim was herbicidally active, or whether both forms as detected by the residue analytical methods were herbicidally active. [redacted] CB has concluded the issue is resolved and no further data are required.

In the method validation data requirements for the compound specific method RM-26D-1, the petitioner is correct in that recovery data from soybeans are needed for either clethodim, clethodim sulfoxide, or clethodim sulfone, and the analogous sethoxydim compound. The petitioner is correct that the fortification levels of 5.0 ppm, 1.0 ppm and 0.05 ppm are

2

acceptable. In the letter petitioner did not mention that CBTS also requested either 5-hydroxyclethodim sulfoxide or 5-hydroxy clethodim sulfone in soybean recovery data at 5.0 ppm, 1.0 ppm, and 0.05 ppm. CBTS notes that the petitioner has already presented recovery data for 5-hydroxyclethodim sulfoxide in MRID # 416234-01. The recovery data are from soybean seeds for clethodim sulfoxide and 5-hydroxyclethodim sulfoxide at 0.05 ppm, 1 ppm, and 5 ppm. Clethodim sulfoxide and 5-hydroxyclethodim sulfoxide recovery data in cottonseed at 0.05 ppm and 1 ppm were also submitted in this same MRID #. Analogous sethoxydim sulfoxide and 5-hydroxysethoxydim sulfoxide in soybeans recovery data at 5.0 ppm were also presented.

For the revised PMV on compound specific clethodim method RM-26D-1 on soybeans we will request validation of clethodim sulfoxide and 5-hydroxyclethodim sulfoxide at 5.0 ppm, 1.0 ppm (the proposed tolerance in cottonseed), and 0.05 ppm (limit of sensitivity); and for sethoxydim sulfoxide and 5-hydroxy sethoxydim sulfoxide at 5 ppm.

At a later time before Method RM-26D-1 is published in PAM-II the petitioner needs to present additional sethoxydim sulfoxide and 5-hydroxysethoxydim sulfoxide recovery data at 1.0 ppm and 0.05 ppm in soybeans using method RM-26D-1. These data are not necessary to establish clethodim tolerances at this time.

The petitioner is correct that for the compound specific method validation data are necessary in beef liver for either clethodim, clethodim sulfoxide or clethodim sulfone and the analogous sethoxydim compound(s). We propose only one fortification level for beef liver at 0.2 ppm. The petitioner has presented method validation data at 0.2 ppm in beef liver for clethodim sulfoxide and sethoxydim sulfoxide. The petitioner is correct that no further method validation data are required for method RM-26D-1 on beef liver. In the revised PMV on Method RM-26D-1 CB will request validation in beef liver for clethodim sulfoxide and sethoxydim sulfoxide only at 0.2 ppm

The petitioner is correct that for the compound specific method validation data are necessary in milk for either clethodim, clethodim sulfoxide, or clethodim sulfone and the analogous sethoxydim material. The Petitioner has presented clethodim sulfoxide validation data in milk at 2 levels; ie, the proposed tolerance of 0.05 ppm and the limit of detection of 0.02 ppm. For the PMV and to establish the proposed clethodim tolerance we will accept sethoxydim sulfoxide at 0.05ppm. As with soybeans the petitioner needs to generate additional method validation data using Method RM-26D-1 for sethoxydim sulfoxide at 0.02 ppm in milk prior to publishing the method in PAM-II. The petitioner is correct we need method validation data at 0.02 ppm and 0.05 ppm in milk for the S-methyl clethodim sulfoxide with or without the corresponding sethoxydim analog for method RM-26D-1. Without method validation data for S-methyl clethodim sulfoxide

the PMV on Method RM-26D-1 can not be completed, and the tolerance can not be established.

For the revised PMV on the compound specific clethodim method RM-26D-1 in milk we will request validation of clethodim sulfoxide at 0.02ppm and 0.05 ppm; and for sethoxydim sulfoxide at 0.05 ppm. Once CBTS has received and reviewed recovery data for S-methyl clethodim sulfoxide in milk at 0.02 ppm and 0.05 ppm we will request additional PMV validation. CB points out the proposed time line to complete an expedited PMV is moving forward as long as we do not have the petitioner's validation data.

At a later time before Method RM-26D-1 is published in PAM-II the petitioner needs to present additional sethoxydim sulfoxide 0.02 ppm in milk using method RM-26D-1. These data are not necessary to establish clethodim tolerances at this time.

CB reiterates **FOR THE COMPOUND SPECIFIC METHOD QUANTITATION OF ALL RECOVERIES IS NECESSARY; HOWEVER, THESE RECOVERIES NEED NOT IN ALL CASES EXCEED 70%. ANY RECOVERY DATA ARE ACCEPTABLE.** The 40% recovery value cited was used for discussion and/or illustration purposes. These recovery data were found as the petitioner said in MRID# 416234-01 dated August 1990 and titled "Confirmatory Method for the Determination of Clethodim and Clethodim Metabolites in Crops, Animal Tissues, Milk and Eggs." This document will be forwarded to ACB as part of the revised PMV request.

The petitioner is <u>NOT</u> totally correct that the only new method validation data for method RM-26D-1 is for the S-methyl clethodim sulfoxide at 2 levels. At a later time frame, but prior to the publication of the method RM-26D-1 in PAM-II, additional recovery data are necessary for sethoxydim metabolites in milk and soybeans.

We are in agreement that the S-methyl clethodim metabolites are seen only in ruminants and from feeding of parent compound at high levels. We take exception to the petitioner's view that he would not ever expect cows to be exposed to parent compound. This could occur, however, in pesticide misuse cases. The analytical method validation for S-methyl clethodim metabolites in milk is the analytical tool the Agency plans to provide the enforcement laboratories to enforce tolerances and to do proper pesticide use/misuse investigations.

Valent's Attachment 2 was a copy of their August 24, 1989 letter requesting a conference to discuss residue analytical methods. This CBTS declined to do as our review of the petition had just begun. Our notes of a telecon between R.S.Quick and J.Miller on 8/22/89 is that CB does not attend conferences on petitions under active review. We did state that common moiety methods <u>**in general**</u> are acceptable enforcement procedures.

However, the petitioner is expected to present a concurrent confirmatory procedure, otherwise this is a major deficiency.

Valent's Attachment 3 was a copy of their September 11, 1989 letter summarizing a telecon on the need to confirm on methods. Please note CB (AKA DEB) responded to this request in our January 30, 1990 review by M.J. Nelson. CB reiterates that "in principle" we concurred at that time with the petitioner's proposal that the common moiety method can be used as the primary enforcement method, and the specific method serve as a confirmatory procedure to differentiate between clethodim and sethoxydim when necessary. CB noted as of January 30, 1990 the Branch had not received the specific method for review. We reiterated that the petition as a whole was under active review.

The petitioner is now requesting a meeting on granting a conditional registration. This is an issue for RD to decide.

CB feels the claim of refusing to meet with Valent to discuss methods is a bit strong and unfair. Generally, we do not meet with petitioners when a petition is under active review (as it was in this case). We point out there were numerous method related deficiencies encountered with both methods from the very beginning. Once the methods were presented correctly written and were properly validated, then CB could decide on appropriate PMVs. We are surprised that the petitioner had no indication additional method validation data were necessary. We feel that the petitioner was forewarned by the common moiety method PMV as to what clethodim plus its metabolites and at what levels would also be included in any compound specific method PMV. To us it was entirely logical that the compounds and levels chosen for the common moiety method PMV in October of 1990 would be the same ones and levels chosen for a compound specific PMV later.

CB points out the established sethoxydim tolerances in soybeans and fuzzy cottonseed are based on active crop field trial residue data. The proposed clethodim tolerances in soybean and fuzzy cottonseed are based on actual crop field trial residue. The secondary tolerances in both poultry and eggs are based on results of the respective feeding studies. CB reiterates we recommend for tolerances no higher than necessary.

Whether or not Poast® and Select® will be used on the same crop due to economic, or other reasons can not be predicted, but there is a possibility that it could happen. Thus, there is a need for strong enforcement residue analytical methods. The petitioner being willing to add label language to prohibit use of Select and Poast on the same crop in the same growing season is helpful. CB points out this will not stop misuse but will make it easier for enforcement agencies to successfully prosecute pesticide misuse cases.

cc: R.F.,Circ(7),Reviewer(FDG),PP#9F3743,TOX,H.Hundley (ACB-Beltsville), R.D.Schmitt, Chief, PIB/FOD (Furlow).

H-7509C:CB:CBTS:Reviewer(FDG);CM#2:Rm814B:557-0826:vg:5/1/91:edit:fdg:5/2/91.

RDI:SectHd:RSQuick:5/6/91:BrSRSci:RALoranger:5/6/91.